

### REMARKS

Claims 1-4 and 23-28 are currently pending to which the Examiner provides two obviousness rejections.

I. Rejections Under Obviousness

- A. Claims 1-4 and 23-24 are rejected under 35 USC § 103(a) as allegedly being unpatentable over United States Patent No. 6,726,923 To Iyer et al., in view of United States Patent No. 6,068,654 To Berg et al.
- B. Claims 25-28 are rejected under 35 USC § 103(a) as allegedly being unpatentable over United States Patent No. 6,726,923 To Iyer et al., in view of United States Patent No. 3,902,497 To Casey.

I. **The Claims Are Not *Prima Facie* Obvious**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not meet these criterion. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

A. **Claims 1-4 & 23-24 Are Not Obvious Under Iyer et al. and Berg et al.**

1. **There Is No Motivation To Combine The Teachings Of Iyer et al. And Berg et al.**

The Applicants argue that Berg et al. is not relevant to perivascular placement of any types of material, especially those contemplated by Iyer et al. Moreover, Berg et al. teaches a device that is intraluminally inserted into a vessel:

Next, the tubular anchor structure is inserted substantially coaxially in the patient's tubular body structure, adjacent to the aperture in the side wall of the tubular body structure ... After the tubular anchor structure is inserted into the tubular body structure ... it is preferably circumferentially expanded ...

*Berg et al. col 2 ln 36-42.* The Examiner should note that Berg et al. describes intravascular stents as one possible embodiment for a tubular body structure:

... tubular anchor structure 30 may be a modified metal tube, formed from expandable metal - ... this type of structure is frequently found in stents used to prevent collapses of tubular body structures, and tubular anchor structure 30 could be a converted stent, possibly with some modifications.

*Berg et al., col 5 ln 45-53.* Iyer et al. discusses the drawbacks of stent technology:

Stents are either "balloon-expandable" or "self-expanding" and when deployed endovascularly, abut against the inner vessel wall. Whether or not a stent is placed, this form of treatment has a high risk of failure ...

*Iyer et al. col 3 ln 1-4.* Consequently, upon reading Berg's teachings one having ordinary skill in the art would not be motivated to look to Iyer's perivascular wrap in order to improve Berg's intravascular tubular anchor structure technology.

Further, the Examiner admits that Iyer et al. teaches:

... [a] ... matrix ... capable of being wrapped around tissues of a human body, because it is perivascularly wrapped around site of interest.

*Office Action pg 2, para 3.* and fails to teach:

... a matrix with annular shape and radial edge ...

*Office Action, pg 2 para 4.* In an effort to fill this deficiency, the Examiner asserts Berg et al. for the following teaching:

However, as revealed by Berg et al., T-shaped Joint location of vascular vessel is normally in the shape of a circle, and the connector of the joint is in the shape of annular. See, the figures.

*Office Action, pg 3 para 4.* The Examiner offers Berg et al. only for a simple description of anatomy without any discussion of how the devices described in Berg et al. are relevant to the devices described in Iyer et al. The Examiner is asked to take note of the recent Supreme Court opinion which says that a specific showing by the Examiner is required:

Often, it will be necessary ... to look to interrelated teachings of multiple patents ... in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See, *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“[R]ejection on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

*KSR v. Teleflex, Slip Op No. 04-1350 (April 30, 2007).* Clearly, upon reading the teachings of Iyer et al., one having ordinary skill in the art would not be motivated to look to Berg’s intravascular tubular anchor structure technology to improve Iyer’s perivascular wrap technology.

Based upon this analysis alone, the Applicants respectfully request the Examiner to withdraw the present rejection.

**2. Iyer et al. and Berg et al. Do Not Teach All The Claim Limitations**

Even if Iyer et al. and Berg et al. were properly combined (which they are not) a *prima facie* case of obviousness would still fail. Even when improperly combined they fail to teach all the Applicants’ claim limitations. Neither reference discloses, teaches or suggests an annular surgical wrap comprising a centrally located hole, a radial edge and a drug related to rapamycin.

Based upon this analysis alone, the Applicants respectfully request the Examiner to withdraw the present rejection.

**3. Iyer et al. And Berg et al. Provide No Expectation Of Success**

As pointed out above, neither Iyer et al. nor Berg et al. teach an annular surgical wrap comprising a centrally located hole, a radial edge and a drug related to rapamycin. Consequently, it is not possible for either of these references to contain any teachings that the Applicants presently claimed embodiment might reasonably be successful.

Based upon this analysis alone, the Applicants respectfully request the Examiner to withdraw the present rejection.

**B. Claims 25-28 Are Not Obvious Over Iyer et al. And Casey.**

**1. There Is No Motivation To Combine The Teachings Of Iyer et al. And Casey**

Casey describes a surgical sponge having requirements that are quite different than Iyer's surgical wrap:

A sponge should have high absorptive capacity, should absorb fluids, particularly blood ...

*Casey, col 3 ln 4-5.* This device is quite different from the drug-eluting device described by Iyer et al. and admitted as such by the Examiner:

Iyer describes a drug-eluting biodegradable matrix ...

*Office Action, pg 2 para 3.* If Iyer et al. were to use the sponge device as taught by Casey, drug elution would not be possible. Clearly, upon reading the teachings of Casey, one having ordinary skill in the art would not be motivated to look to Iyer's perivascular wrap in order to improve Casey's surgical sponge technology.

Further, the Examiner has admitted that:

Iyer et al. do not teach ... the biodegradable material [to] be oxidized regenerated cellulose.

*Office Action pg 3 para 6.* The Examiner then asserts Casey for the alleged teaching that:

... oxidized regenerated cellulose is a well-known biodegradable material absorbable in tissues.

*Office Action, pg 3 para 7.* First, the Applicants question that a statement appearing in Casey's "Description Of The Prior Art" section is properly considered "a teaching". Second, the Examiner has, apparently, not realized that Casey is actually criticizing the use of oxidized regenerated cellulose:

Commercially, an oxidized regenerated cellulose is available, as in a gelatin foam distributed in sheet form. ... Under some conditions, the gelatin foam causes bile cysts.

*Casey, col 2 ln38-41*. The Examiner should now realize that Casey only discloses that oxidized regenerated cellulose has been used in a gelatin foam (and creating side effects), and not the use of oxidized regenerated cellulose alone. Clearly, upon reading the teachings of Iyer et al., one having ordinary skill in the art would not be motivated to look to Casey's surgical sponge technology in order to improve Iyer's perivascular wrap technology.

Based upon this analysis alone, the Applicants respectfully request the Examiner to withdraw the present rejection.

**2. Iyer et al. and Casey Do Not Teach All The Claim Limitations**

Even if Iyer et al. and Casey. were properly combined (which they are not) a *prima facie* case of obviousness would still fail. Even when improperly combined they fail to teach all the Applicants' claim limitations. Neither reference discloses, teaches or suggests an annular surgical wrap comprising a centrally located hole, a radial edge and a drug related to rapamycin. The Examiner should take particular note that Casey fails to even mention that any drug (much less rapamycin) should or could be impregnated into the surgical sponge.

Based upon this analysis alone, the Applicants respectfully request the Examiner to withdraw the present rejection.

**3. Iyer et al. And Casey Provide No Expectation Of Success**

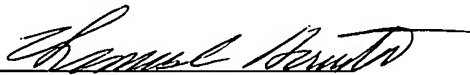
As pointed out above, neither Iyer et al. nor Casey teach an annular surgical wrap comprising a centrally located hole, a radial edge and a drug related to rapamycin. Consequently, it is not possible for either of these references to contain any teachings that the Applicants presently claimed embodiment might reasonably be successful.

Based upon this analysis alone, the Applicants respectfully request the Examiner to withdraw the present rejection.

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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By:   
Thomas C. Howerton  
Reg. No.: 48,650

Medlen & Carroll, LLP  
101 Howard Street, Suite 350  
San Francisco, CA 94105  
617-984-0616